



**\*\*\* One Form A only per applicant/PQ Holder \*\*\***

**MANDATORY**

<b>Registered Company Name:</b>		
<b>License Issuing Country:</b>		
<b><u>Manufacturing site address:</u></b>		
Road name & number:		
Complement:		
Postal code:	City:	Country:
<b>Manufacturing site web address:</b>		
<b>Manufacturing site contact number</b>		
Country code:	Area code:	Telephone:
<b><u>Postal address (if different):</u></b>		
Road name & number:		
Complement:		
Postal code:	City:	Country:
<b>Manufacturing site web address:</b>		
<b>Manufacturing site contact number</b>		
Country code:	Area code:	Telephone:
<b>Contact person 1 name:</b>		
<b>Contact person email address:</b>		@
<b>Contact person name contact number:</b>		
Country code:	Area code:	Telephone:
<b>Contact person 2 name:</b>		
<b>Contact person email address:</b>		@
<b>Contact person name contact number</b>		
Country code:	Area code:	Telephone:

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## SECTION 2. LICENSING - MANUFACTURER LICENCES

**MANDATORY**

**IMPORTANT:** Only a valid **Business Registration** document is acceptable as licence.

**Translations** - Any original document in languages other than English must be accompanied by an official notarized English translation.

**INSTRUCTIONS:** Complete the information in Table 2 below.

**One (1) certified copy (.pdf)** of each licence must also be submitted.

Manufacturers that do not provide valid licences will not be considered.

The submission of invalid licences will result in the automatic suspension of all of the manufacturer's products until valid licenses are provided.

Table 2 – Mandatory Licencing

	Formal document no.	Issue date (DD-MMM-YY)	Expiry date (DD-MMM-YY)
<b>MANDATORY: Business Registration (Company license)</b>			
<b>Optional:</b> Manufacturing license			
<b>Optional:</b> Other:.....			

## SECTION 3. CERTIFICATION - MANUFACTURER CERTIFICATES

**MANDATORY**

**IMPORTANT:** **Certificates expiring before July 14<sup>th</sup> 2026** must be accompanied by a copy of a renewal request letter. This is a **mandatory** requirement.

**A website link to a certification authentication page is mandatory** for certification verification. **PLEASE VERIFY THAT WEBLINK FUNCTIONS.**

**INSTRUCTIONS:** Complete the information in Table 2 below.

**One (1) certified copy (.pdf) of each certificate** is required.

**Translations** - Any original document in languages other than English must be accompanied by an official notarized English translation.

**Manufacturers that do not provide valid certificates will not be considered.** Email confirmation of a pending certificate validation will not be accepted.

The submission of invalid certificates will result in the automatic suspension of all manufacturer products until valid certificates are provided.

All certification bodies should be ILAC accredited.



Table 3 – Mandatory Certification

Requirements per IMD-PQS category	Certificate	Certificate accreditation year (e.g. 2015)	Certification authority (certified by)	Website link for certification verification <b>MANDATORY</b>	Expiry date (DD-MMM-YY)
<b><u>ALL CATEGORIES</u></b> <b>Except E008 &amp; E013</b>	ISO 9001:2015*				
E001 E003 E004	ISO 14001:2015*				
E008 E013	ISO 13485:2016*				
Optional	93/42/EEC				
Other approval marks (e.g. CE, UL, FDA or EMA):					

#### SECTION 4. CHANGES TO MANUFACTURING INFORMATION

**MANDATORY**

**INSTRUCTIONS:**

If no changes have occurred, or are expected to occur, between April 2025 and March 2026, please tick **NO**.

If changes **HAVE** occurred, manufacturers must submit documentation verifying the amended information.

Table 4 – Changes to manufacturing information



Performance,  
Quality &  
Safety



World Health  
Organization

		<i>Please provide details of changes:</i>
Have there been any changes to the <b>company name</b> and/or <b>status</b> in the last 12 months?	YES <input type="checkbox"/> NO <input type="checkbox"/>	
Have there been any changes to the <b>product manufacturing site address</b> in the last 12 months?	YES <input type="checkbox"/> NO <input type="checkbox"/>	